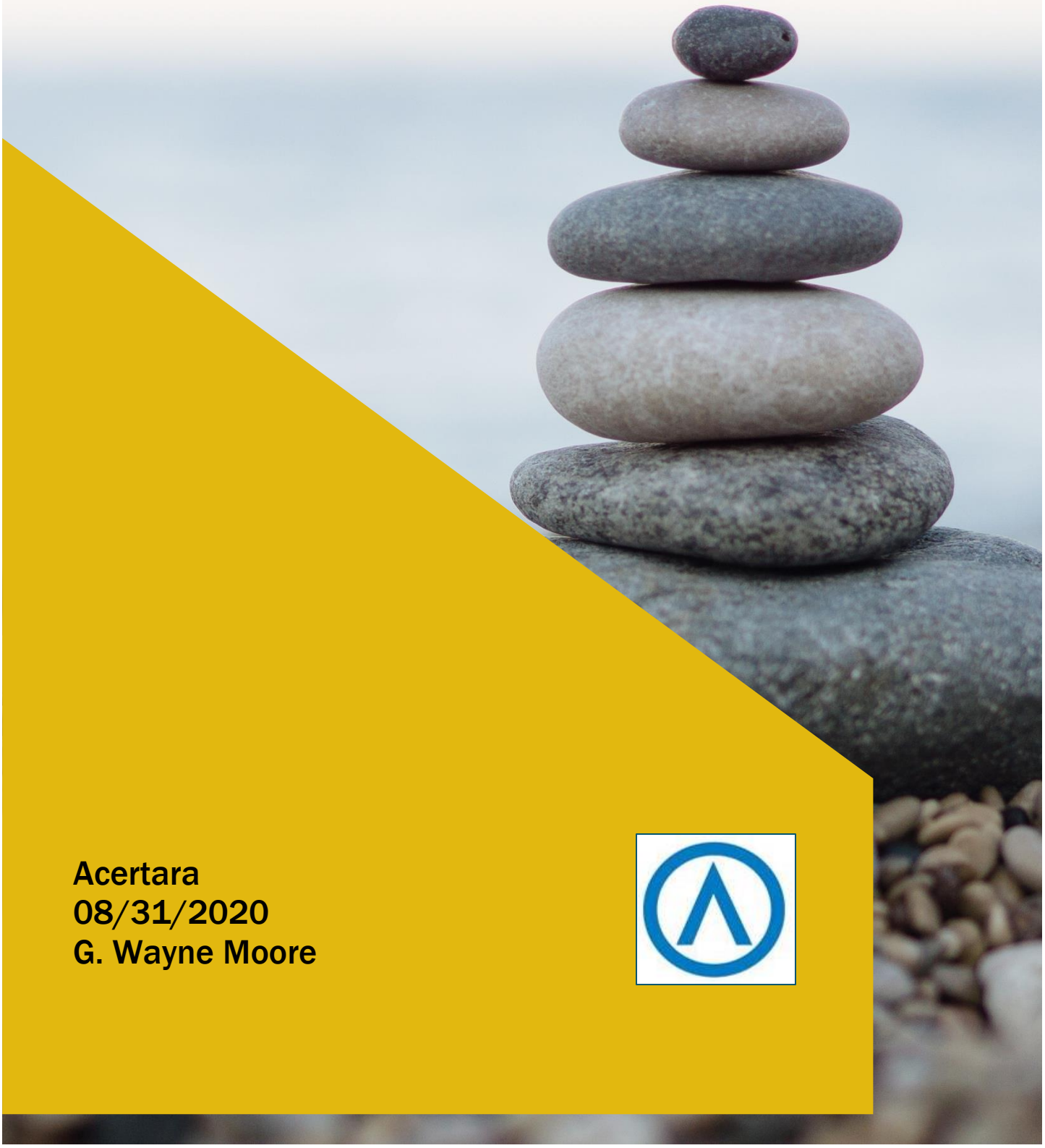
De-Risking the Medical Device Supply Chain

Observations from the COVID-19 Pandemic



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INTRODUCTION

Negative Production Externalities

The global medical device supply chain has simultaneously grown exponentially and become increasing fragile since the movement to offshore manufacturing began in earnest more than 30 years ago. In many cases entire infrastructures from manufacturing to logistics had to be created in selected countries to take advantage of inexpensive labor and various tax and tariff incentives. Unfortunately, this offshoring paradigm all too often came at the expense of American jobs and American capabilities. The by-product of offshoring can be thought of as a negative production externality, i.e., the cost to American society was much higher than the savings recognized by manufacturers. Normally an externality does not directly affect the manufacturer and offshoring seemed to be working well fiscally for them during normal times. However, in early 2020, an abnormal event occurred that stunned the global medical device supply chain – the pandemic known as COVID-19. Since the onset of COVID-19, manufacturers have been increasingly reconsidering the wisdom of using an off-shore supply chain strategy, especially when a sole-source arrangement is in place. Additionally, COVID-19 revealed to the general populace of the US just how many critical components and materials are produced in countries that may not have the best of intentions toward the US politically and who have turned those products into political bargaining chips. Further, long-standing questions of theft of intellectual property in certain countries has raised the costs of doing business in those countries and has compromised patent and copyright integrity.

Reshoring, or bringing back the supply-chain to the United States, is one of the strategies now being considered to mitigate the potential damage to the supply chain any future events may cause. A big question regarding a reshoring strategy is "*does the capability and capacity to do so reside in the US?*".

The Medical Imaging Device Supply Chain

Parts, materials, and components that are used to assemble a complex finished medical imaging device, can number in thousands, and are often made in multiple countries around the world. A disruption in the availability of a single part or component in one country can have a domino effect on parts and components in other countries that ultimately delay the final production of any given system. For example, a finished ultrasound probe (transducer) may be comprised of an array manufactured in Korea, a probe cable manufactured in Japan, plastic enclosure parts made in China, and a finished probe connector manufactured in India. If the supply chain fails in just one of

these countries the subsequent ripple effect means that a finished probe cannot be produced, resulting in the ultrasound system that the probe is connected to unable to be used for its intended use. Most manufacturers with whom we have spoken have indicated that, in many circumstances, their offshore suppliers are single-source; there is not a back-up strategy should that supplier, or the country they are located in, be unable to produce or ship out of the country critical parts and components.

In its recent 2020 report on the State of Manufacturing, Fictiv's (www.fictiv.com) research of manufacturing found the following rather startling data related to COVID-19 disruption effects:

- 83% of respondents agreed that COVID-19 has been an extreme test to their supply chain
- 95% said they were currently working to increase their supply chain agility
- 91% plan to adopt dual and triple-sourcing strategies
- 84% say they will be more cautious about offshoring, and
- 73% have minimized or have plans to minimize reliance on China

These survey results illustrate the potential side-effects of using a high-risk (single source) supply chain based simply on saving a few pennies per part. We now know that a pandemic can shut down the business completely erasing in a few months or less the benefits of low-cost production. This current pandemic has also revealed that even if offshore suppliers were not shut down completely, neither could they scale production to meet an increased demand for certain COVID-19 critical devices, such as ventilators, or certain types of imaging components such as ultrasound probes and point-of-care handheld ultrasound units.

COVID-19 Observations of the Medical Device Supply Chain

Not far into the current pandemic my email and phone activity spiked with calls from various ultrasound manufacturers regarding how we might be able to help them with certain parts, components, and manufacturing capacity of ultrasound devices, (in this case specifically ultrasound probes because of catastrophic supply-chain failures). For example, some manufacturers had plenty of arrays (made in country X), but no cables (made in country Y) to attach them to. Other manufacturers were being inundated with requests from hospitals for POC ultrasound units with no way to scale their operations to produce and deliver. Some start-ups who had not yet obtained FDA 510(k) clearance for their POC ultrasound units wanted to know if we could manufacture them under the

Emergency Use Authority, or EUA (see below). In short, there was a period of panic, a time of distress. Randall Lane, Chief Content Officer of Forbes recently said that, "*success stems from reinvention during periods of strength, rather than during distress*." It seems reasonable that with respect to the supply chain now would be a good time to look at some reinvention – domestic reinvention.

Medical Imaging Device Supply Chain – Emergency Use Authorization (EUA)

In response to device shortages caused by the effect of COVID-19 on the supply chain, the US Food and Drug Administration used its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. These devices will almost certainly be re-called from the market once the pandemic emergency is over. Heroic efforts by non-medical industries, such as auto makers were scrambling to re-tool their manufacturing floors to produce ventilators and other COVID-19 critical devices. While this activity was clearly necessary for the emergency our hospitals and caregivers faced, this approach would obviously not be sustainable for future development. We have now seen that substantial device shortages can arise during a pandemic, due in large part to the extreme strain placed on the global supply-chain, and as an industry we must plan for future eventualities. The US FDA has been and is currently working with healthcare providers to gain clearer insight of the real-time supply and potential surge in demand for various medical devices coupled with current capacity to produce in the US. This quantitative assessment is key to justify incentivizing an increase in domestic manufacturing with the goal of creating a more predictable, robust, and sustainable domestic medical device supply-chain.

De-Risking the Medical Imaging Device Supply Chain

At the risk of sounding self-serving I posit that an ideal candidate for a second or third source would be a technology focused, independent, and entrepreneurial company located somewhere in the middle of the United States close to a major airport. This company should have a mature Quality Management System, a dedicated team of experienced employees, and an infrastructure that could rapidly adapt and scale to the meet the needs of the manufacturer. A partnership with such a company could evolve that would take care of an immediate market stress, to a long term safe-harbor guarding against and mitigating future unanticipated events that crash their primary supply-chain. This reshoring process would have the effect of bringing jobs and skills back to the United States providing the manufacturer with a trusted domestic partner that it could invest knowledge, time, and resources into, and rely on when unanticipated events occur.

A true partnership arrangement could also be an asset to the manufacturer even when things are going smoothly with its primary supply chain. Opportunities may arise in times of unanticipated scalability requirements and volume overloads could be shifted toward a domestic partner. Lastly, a domestic partner is also a lesser threat to intellectual property theft and seeking a win-win with the manufacturer rather than "what I can get out of them".

Conclusion

Anticipating every eventuality is, of course not possible, but there are solid business reasons for at least analyzing and de-risking (through reinvention) those operations of a business that could lead to a catastrophic event with production and delivery; such as a major supply-chain failure. In 2020 the risk-analysis matrix should also include a new line item - pandemic. Reshoring is one important way to create a second and even third source for the production of key components, parts, and manufacturing services. Reshoring develops the capacity, capability, and jobs in the US where operations can continue during a global crisis providing an uninterrupted supply of mission-critical medical devices to our valued healthcare providers who care for our number one priority - patients.

About the Author

A 40-year veteran of the diagnostic ultrasound market Wayne has held senior level positions with several major medical equipment manufacturers, including Honeywell Medical Systems and Siemens Medical Solutions. Over his career, Wayne has been directly involved in the development and commercialization of more than 20 technologically intensive ultrasound systems. He is widely published in diagnostic ultrasound literature, a sought-after speaker at medical imaging conferences, has served as an expert witness in multiple ultrasound litigations and is co-Author on more than 25 US and International ultrasound related patents. Wayne is the 2020 Ultrasound Chair for the MITA (Medical Imaging and Technology Alliance) Ultrasound Section and is a co-Chair on the Output Standards Committee of the AIUM (American Institute of Ultrasound in Medicine). Wayne obtained his MBA from the University of Denver – Daniels College of Business.

He was elected as a Fellow of the American Society of Echocardiography (FASE) in 2009.